

ORAL ARGUMENT REQUESTED

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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Plumbers' Local Union No. 690 Health Plan :  
and Delaware Valley Health Care Coalition, :  
:  
Plaintiffs, :  
:  
vs. :  
:  
Sanofi, S.A., Sanofi US Services Inc., Sanofi- :  
Aventis U.S., LLC, Fidia Farmaceutici S.p.A., :  
Fidia Pharma USA Inc., Accenture PLC :  
(ACN), Deloitte LLP, Christopher A. :  
Viehbacher, Dennis Urbaniak, Raymond :  
Godleski, Thomas C. Valentine, Doe :  
Defendants A-Z, ABC Corporations AA-ZZ, :  
and XYZ Partnerships and Associations :  
AAA-ZZZ, :  
:  
Defendants. :  
-----X

Civil Action No. 2:15-00956-  
KM-MAH

**Motion Date: December 5, 2016**

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MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT FIDIA  
PHARMA USA INC.'S MOTION TO DISMISS THE SECOND AMENDED  
CLASS ACTION COMPLAINT

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HERRICK, FEINSTEIN LLP  
One Gateway Center  
Newark, New Jersey 07102  
(973) 274-2000  
Attorneys for Fidia Pharma USA Inc.

On the Brief:

Ronald J. Levine, Esq.  
rlevine@herrick.com  
David R. King, Esq.  
dking@herrick.com

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### **PRELIMINARY STATEMENT**

Defendant Fidia Pharma USA Inc. (“Fidia USA”) respectfully submits this memorandum of law in support of its motion to dismiss plaintiffs Plumbers’ Local Union No. 690 Health Plan’s (“Plumbers”) and Delaware Valley Health Care Coalition’s (“DVHCC,” and together with Plumbers, “Plaintiffs”) Second Amended Class Action Complaint (“Second Amended Complaint”) under Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure.

The core of the action remains unchanged in the Second Amended Complaint. Plaintiffs allege that Fidia USA, along with other named defendants, reported inflated prices to the government for Hyalgan which Plaintiffs contend impacted their private reimbursements for prescriptions of the product.<sup>1</sup>

Plaintiffs made some minor changes in the Second Amended Complaint, including dropping a defendant (Genzyme Corporation), adding a plaintiff (DVHCC), adding new, state-specific causes of action, and adding a few meager allegations in a weak attempt to substantiate their claims against Fidia USA. Plaintiffs, however, failed to add anything that would warrant a different fate than that of the First Amended Complaint -- dismissal. In dismissing the First

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<sup>1</sup> Plaintiffs also allege that certain of the named defendants provided illegal kickbacks to promote diabetes products. These claims are not directed at Fidia USA and therefore are not addressed herein.

Amended Complaint, this Court noted the total absence of factual allegations against either of the Fidia defendants:

The [First Amended Complaint] is devoid of specifics regarding Fidia . . . [The allegations against Fidia USA and Fidia S.p.A.] are conclusory allegations that lack any specific factual allegations of fraudulent or deceptive action by Fidia. Fidia licensed Hyalgan to Sanofi and allegedly knew about Sanofi's acts or advised Sanofi, in some unspecified way, regarding "strategy" relating to samples. There are no further allegations as to Fidia's role in any illicit action as it relates to [Plumbers]. No specific factual examples are given. There are no allegations showing that any [Plumbers] beneficiary in Pennsylvania or New Jersey was affected. That Fidia regained control of Hyalgan distribution in 2011 is irrelevant: the alleged time period for the sample infractions is 2005-2009.

*See* Opinion, Dkt. No. 89, at III.1.ii. These same deficiencies -- and more -- pervade the Second Amended Complaint, and thus Plaintiffs' claims against Fidia USA remain insufficient as a matter of law.

First and most fundamentally, Fidia USA is alleged to have been incorporated in May 2011, as a wholly-owned subsidiary of Fidia Farmaceutici S.p.A ("Fidia S.p.A."). *See* Second Amended Complaint, ¶ 24. Plaintiffs conflate these two separate entities by collectively referring to them as "Fidia" in an attempt

to obfuscate Fidia USA's utter lack of involvement with any of the alleged conduct. *Id.* at ¶ 25.<sup>2</sup>

Despite Plaintiffs' attempts to blur the line between these two entities, Fidia USA, which admittedly was not incorporated until 2011, has no connection whatsoever with the allegations in the pleading. The Second Amended Complaint references a 1997 co-promotion agreement, to which Fidia S.p.A. was a party (the "Co-Promotion Agreement"), that was allegedly terminated in September 2000<sup>3</sup> -- well before the incorporation of Fidia USA. *Id.* at ¶¶ 73, 75. This terminated Co-Promotion Agreement is the basis for Plaintiffs' purported "belief" that Fidia USA had direct knowledge and involvement in the alleged marketing and sales activities of defendants Sanofi, S.A., Sanofi US Services Inc., and Sanofi-Aventis U.S., LLC (together, the "Sanofi Parties").

Moreover, the alleged wrongful conduct involving Hyalgan marketing described in the Second Amended Complaint purportedly occurred from 2005 to 2009 -- years before the creation of Fidia U.S.A.. *See, e.g., id.* at ¶¶ 24; 75; 77; 99; 106; 107; 115; 119; 139; 145; 148; 149; 163; 164; 174. Plaintiffs engage in naked

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<sup>2</sup> This is not to suggest that the Second Amended Complaint states a claim against Fidia S.p.A. either.

<sup>3</sup> The Amended Complaint alleged that the Co-Promotion Agreement was terminated in 2010. *See* First Amended Complaint, ¶ 71. The Second Amended Complaint alleges that it was terminated in 2000. *See* Second Amended Complaint, ¶ 75. Both alleged termination dates pre-date the incorporation of Fidia USA. *See* Second Amended Complaint, ¶ 24.



speculation when they suggest that Fidia S.p.A. and Fidia USA were involved in the alleged wrongful conduct. Lacking actual facts, Plaintiffs are forced to resort to a conspiracy-theory approach. Thus, Plaintiffs add allegations about an August 2011 letter, which simply informs Hyalgan prescribers that Fidia S.p.A. intended to promote, distribute, and sell Hyalgan through its subsidiary, Fidia USA, and that the distribution and reimbursement process would remain the same. *See, id.* at Ex. 1. Rather than reading the letter for what it is -- a straightforward letter informing prescribers who would be distributing Hyalgan to them going forward -- the Plaintiffs creatively distort the letter into a smoking gun admission that Fidia S.p.A. and Fidia USA promised to work with the prescribers (in a form letter, no less) to embark on a complex scheme to defraud patients and the Plaintiffs. The letter, of course, does not support any claim of wrongdoing against Fidia USA or anyone else, and does nothing to cure the glaring lack of actual factual allegations against Fidia USA observed by the Court in the First Amended Complaint.

The claims also fail as a matter of law because they are barred by the doctrines of release and *res judicata*. Moreover, Plaintiffs have not adequately alleged a claim for consumer fraud under New Jersey, Pennsylvania, California and Maryland law, the claims for unjust enrichment and conspiracy are likewise deficient, and DVHCC lacks standing. These arguments are fully briefed by Fidia USA's co-defendants and Fidia USA incorporates them herein by reference.

## **ARGUMENT**

### **POINT I**

#### **THE SECOND AMENDED COMPLAINT IS DEVOID OF ALLEGATIONS OF WRONGFUL CONDUCT BY FIDIA USA**

##### **A. Fidia USA Was Not Incorporated Until After the Alleged Wrongful Conduct of Sanofi.**

Fidia USA cannot be liable under any theory for the conduct alleged in the Amended Complaint because it did not even exist until May 2011 -- years after the alleged wrongful conduct involving Hyalgan occurred (2005-2009). *See* Second Amended Complaint, ¶¶ 24; 41; 75; 77; 106; 107; 110; 115; 119; 137-139; 145; 148; 149; 163; 164; 174.

Moreover, Plaintiffs' new allegation based on the August 2011 letter fails to support Plaintiffs' claim that Fidia USA can somehow be responsible for the wrongful conduct alleged to have occurred between 2005 and 2009, or Plaintiffs' new and similarly unsupported theory that wrongful conduct continued after 2009.

The August 2011 letter is straightforward and to the point in informing Hyalgan prescribers that Sanofi U.S. LLC would no longer distribute Hyalgan, and that Fidia USA would handle U.S. sales of the product:

on September 24, 2011, the rights to distribute HYALGAN (sodium hyaluronate) in the United States will transfer from Sanofi U.S. LLC to Fidia Farmaceutici S.p.A. (Fidia), the product's Italian owner and manufacturer. After this date, Fidia will promote,

distribute, and sell the product directly in the United States through its wholly owned US subsidiary, Fidia Pharma USA Inc.

*See* Second Amended Complaint, Ex. A. In the “Questions & Answers” section of the letter, prescribers were informed that they “will continue to receive reimbursement for HYALGAN using the same process that [they] have been using.” *Id.*

Based on this letter alone, Plaintiffs reach for the unfounded conclusion that “Fidia committed to continuing the same marketing and sales practices” and that the “free sample practices started by Sanofi continued by Fidia, as a form of discounting to providers intended to reduce the acquisition price prices for Hyalgan.” *Id.* at ¶¶ 82-83. This allegation is insufficient to sustain the action against Fidia USA. It is a quintessential example of a bare and conclusory statement that is insufficient to maintain a cause of action against Fidia USA. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (holding that courts are not bound to accept pleadings that are no more than conclusions); *In re Schering Plough*, 678 F.3d 235, 248 (3d Cir. 2012) (holding that plaintiff cannot survive motion to dismiss by relying on unsupported allegations made on information and belief). Plaintiff’s reliance on the 2011 letter is further belied by their allegations that the improper free sample practices occurred between 2005 and 2009. *See* Second Amended Complaint, ¶¶ 24; 41; 75; 77; 106; 107; 110; 115; 119; 137-139; 145;

148; 149; 163; 164; 174. There is no allegation that even Sanofi continued these purported practices until 2011, thus calling into question what practices, if any, Fidia S.p.A and Fidia continued. Indeed, other than speculation based on this letter, which does not support even an inference of wrongful conduct, Plaintiffs allege no wrongful conduct specific to Fidia USA after 2011.

Accordingly, all claims against Fidia USA should be dismissed with prejudice because Fidia USA could not possibly have been involved in any of the alleged pre-2011 wrongful conduct, and Plaintiffs' wishful speculation fails to support any claim for post-2011 conduct either.

**B. Plaintiffs' Second Amended Complaint Fails to Allege Conduct Specific to Fidia USA.**

Plaintiffs have defined "Fidia" to include both Fidia USA and Fidia S.p.A. By lumping together these two separate corporate entities, Plaintiffs attempt, but fail, to fabricate a claim against Fidia USA. This Court held that the First Amended Complaint was "devoid of specifics regarding Fidia," Opinion, Dkt. No. 89 at III.1.ii. The Second Amended Complaint has not remedied this fatal deficiency. The only allegation relating to Fidia USA added in the Second Amended Complaint pertains to the August 2011 letter. This letter, as discussed above, offers, at best, a bare and conclusory allegation that Fidia S.p.A. regained control of Hyalgan distribution in 2011 and promised that distribution would continue under the same process. This allegation fails to state a claim under any

standard, and certainly falls far short of the specificity required of claims sounding in fraud. Accordingly, the claims should be dismissed.

Where, as here, “allegations of fraud are brought against multiple defendants, the complaint must ‘plead with particularity . . . the [specific] allegations of fraud’ applicable to each defendant.” *Donachy v. Intrawest U.S. Holdings, Inc.*, Civ. No. 10–4038 (RMB/KMW), 2012 WL 869007, at \*2 (D.N.J. Mar. 14 2012) (*quoting MDNet, Inc. v. Pharmacia Corp.*, 147 F. App’x 239, 245 (3d Cir. 2005)). “[C]ollectivized allegations that generally allege fraud as against multiple defendants, without informing each defendant as to the specific fraudulent acts he or she is alleged to have committed, do not satisfy Rule 9(b).” *Weske v. Samsung Elec., Am., Inc.*, 934 F. Supp. 2d 698, 703 (D.N.J. 2013) (*quoting Hale v. Stryker Orthopaedics*, No. 8–337 (WLM), 2009 WL 321579, at \*6 (D.N.J. Feb. 9, 2009)).

Courts have regularly dismissed claims of fraud that “lump” defendants together because such allegations do not satisfy the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). In *Weske*, the court dismissed two fraud claims finding, *inter alia*, that the complaint at issue did not distinguish between two related, but distinct, corporate defendants. *See Weske*, 934 F. Supp. 2d at 703. Similarly, in *Hale*, the court found that the plaintiff’s fraud

allegations against multiple defendants, defined collectively as “Defendants,” did not satisfy pleading requirements. *See Hale*, 2009 WL 321579, at \*6.

Additionally, it is well-settled that a subsidiary is a distinct legal entity, and is not liable for the actions of its parent or sister corporations simply because of the corporate relationship. *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 341 n. 44 (3d Cir. 2010); *see also Alexander v. CIGNA Corp.*, 991 F. Supp. 427, 443 (D.N.J.) *aff’d*, 172 F.3d 859 (3d Cir. 1998) (“[P]arent and subsidiary corporations are distinct legal entities . . . .”). Therefore, even if Plaintiffs had adequately alleged wrongdoing on the part of Fidia S.p.A, that would not support a claim against Fidia USA.<sup>4</sup>

Indeed, even under the lesser standard of Federal Rule of Civil Procedure 8(a), attempting to lump members of a corporate family together under a single defined term, as Plaintiffs seek to do here, has been roundly rejected. *See In re Lithium Ion Batteries Antitrust Litig.*, No. 13-MD-2420 (YGR), 2014 WL 309192 at \*13 (N.D. Cal. Jan. 21, 2014) (dismissing complaint against U.S. subsidiaries absent adequate allegations of conscious participation by the subsidiaries in the alleged conspiracy); *In re TFT-LCD (Flat Panel) Antitrust Litig.*, 586 F. Supp. 2d 1109, 1116-17 (N.D. Cal. 2008); *Swiss Reinsurance Am.*

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<sup>4</sup> The claims against Fidia S.p.A. likewise appear to be defective and subject to dismissal. Those claims are not the subject of this motion and will be addressed if Plaintiffs serves their pleading on Fidia S.p.A.

*Corp. v. Access Gen. Agency, Inc.*, 571 F. Supp. 2d 882, 885 (N.D. Ill. 2008); *Boykin Anchor Co., Inc. v. AT&T Corp.*, No. 5:10-CV-591 (FL), 2011 WL 1456388 (E.D.N.C. Apr. 14, 2011). Accordingly, to the extent Plaintiffs base their claims against Fidia USA on the purported wrongdoing conduct of other Defendants, including Fidia S.p.A., the Second Amended Complaint fails to state a claim against Fidia USA, and must be dismissed.

**C. Fidia USA Was Not a Party to the Co-Promotion Agreement.**

Dismissal is further warranted because Fidia USA is not a party to the contract relied upon by Plaintiffs. A claim against a defendant who is not a party to the contract at issue must be dismissed. *Williamson v. Corr. Med. Servs.*, 494 F. Supp. 2d 285, 287-88 (D. Del. 2007).

Here, Plaintiffs' claims against Fidia USA are based on the allegation that "Fidia," as improperly and collectively defined in the Second Amended Complaint, entered into a contract with the Sanofi Parties. However, Fidia USA is indisputably not a party to the referenced contract. Without this crucial nexus, the claims against Fidia USA fall apart. Accordingly, the claims against Fidia USA fail as a matter of law and should be dismissed with prejudice.

## POINT II

### **EVEN IF FIDIA USA HAD BEEN INCORPORATED BEFORE 2011, THE HYALGAN CLAIM WOULD BE BARRED**

Fidia USA incorporates and relies upon the arguments advanced by Defendants Sanofi US Services Inc., Sanofi-Aventis U.S., LLC, Christopher Viehbacher, Dennis Urbaniak and Raymond Godleski (together, the “Sanofi Defendants”) in their Brief in Support of Their Motion to Dismiss the Second Amended Class Action Complaint (the “Sanofi Brief”) in support of the conclusion that the Hyalgan claim is barred by release and *res judicata*. See Sanofi Brief, Dkt. No. 105-1 at § IV.C.

Briefly stated, Plumbers settled its price-reporting claims against the Sanofi Defendants at the conclusion of a multi-district litigation, *In re Pharmaceutical Industry Average Wholesale Price Litigation* (the “*Average Wholesale Price Litigation*”). In March 2008, the *Average Wholesale Price Litigation* parties executed the Track Two Settlement Agreement and Release (the “Settlement Agreement”) which released not only the defendants in the *Average Wholesale Price Litigation*, but also any “affiliates” of the signatories to the Settlement Agreement. Although the Second Amended Complaint is far from clear, Fidia USA is alleged to be somehow affiliated with Sanofi and therefore is released under the terms of the Settlement Agreement. See Second Amended



Complaint, ¶¶ 3, 18, 73. The Hyalgan claim is also barred under *res judicata* for the reasons discussed in Section IV.C.2 of the Sanofi Brief.

### **POINT III**

#### **PLAINTIFFS FAIL TO STATE A CLAIM FOR CONSUMER FRAUD UNDER NEW JERSEY, PENNSYLVANIA, NEW YORK, CALIFORNIA, OR MARYLAND LAW**

Fidia USA incorporates and relies upon the arguments advanced by the Sanofi Defendants in the Sanofi Brief in support of the conclusion that Plaintiffs cannot state a claim for consumer fraud under New Jersey, Pennsylvania, New York, California, or Maryland law. *See* Sanofi Brief, §§ IV.A and IV.B. For the same reasons advanced therein, Plaintiffs' claims against Fidia USA should be dismissed.

### **POINT IV**

#### **PLAINTIFF DELAWARE VALLEY HEALTH CARE COALITION LACKS STANDING TO PURSUE ANY CLAIMS**

Fidia USA also relies on the arguments advanced by the Sanofi Defendants that the new plaintiff, DVHCC, lacks standing. *See* Sanofi Brief, § III. For the same reasons advanced therein, Plaintiffs' claims against Fidia USA should be dismissed.

## **POINT V**

### **THE UNJUST ENRICHMENT AND CONSPIRACY CLAIMS ARE LIKEWISE DEFICIENT**

Fidia USA incorporates and relies upon the arguments advanced by the Sanofi Defendants in the Sanofi Brief in support of the conclusion that Plaintiffs cannot state claims for unjust enrichment and conspiracy. *See* Sanofi Brief, § V.<sup>5</sup> For the same reasons advanced therein, Plaintiffs' claims against Fidra USA should be dismissed.

## **CONCLUSION**

For the reasons stated herein, and the reasons advanced by the Sanofi Defendants, Fidra USA respectfully requests that the Second Amended Complaint be dismissed in its entirety with prejudice.

Dated: September 12, 2016  
Newark, New Jersey

HERRICK, FEINSTEIN LLP

By: s/David R. King  
David R. King  
dking@herrick.com  
One Gateway Center  
Newark, New Jersey 07102  
(973) 274-2002  
Attorneys for Defendant Fidra Pharma  
USA Inc.

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<sup>5</sup> Plaintiffs appear to have dropped their claim for "disgorgement".